REMARKS

Claims 1-12, 15-26, 29-43, and 47 were rejected on formal and/or art grounds. Applicants appreciate the Examiner's indication of allowable subject matter in claims 13-14, 27-28, and 44-46. Applicants believe that after considering this paper, the Examiner will agree that the rest of the claims, including new claims 48-56, also contain allowable subject matter.

The Invention

As the Examiner will recall, and as explained in the application, the present invention concerns BIER ("biological indicator evaluator resistometer") devices, which may be used to test sterilization processes and biological and chemical indicators, which indicators (e.g., in the size and shape of a coupon) are often used during routine sterilization to make sure that objects subjected to the sterilization (e.g., medical devices used on patients) have been sufficiently sterilized. Biological indicators contain precisely known amounts of specified microorganisms and provide precisely known resistance to sterilization. Chemical indicators are analogous and used in a similar manner. (Application, page 1, line 21, to page 2, line 7)

A BIER device must be flexible (e.g., be able to be used throughout the ranges of interest for the parameters of interest), be able to rapidly provide uniform conditions throughout the chamber in which the biological or chemical indicators are contacted with the antimicrobial agent, and be precisely controllable with respect to all parameters (concentration of antimicrobial agent, exposure time, temperature, and pressure at which the exposure occurs, etc.). (Application, page 2, lines 8-16)

Use of hydrogen peroxide vapor as the antimicrobial agent is relatively new as compared to use of steam and/or ethylene oxide as the antimicrobial agent and presents a number of problems, some of which are unique as compared to the use of older sterilants such as steam and ethylene oxide. For example, hydrogen peroxide immediately starts to decompose as soon as it is vaporized because the stabilizers that help retard or prevent decomposition of the hydrogen peroxide in aqueous solution do not function in the vapor phase (steam and ethylene oxide do not decompose). As a result, hydrogen peroxide vapor must be generated in "real time" (i.e., as it is needed or on demand), particularly for sterilization processes in which the hydrogen peroxide vapor concentration must be maintained above a predetermined minimum. Hydrogen peroxide has a substantially different vapor pressure curve than water (e.g., its normal boiling point is approximately 151°C as compared to water's normal boiling point of 100°C). Accordingly, differential evaporation (i.e., distillation) may occur when an aqueous solution of hydrogen peroxide used to supply the hydrogen peroxide is being vaporized (hydrogen peroxide is readily commercially available as an aqueous liquid solution and it is more convenient to vaporize the entire solution to provide a hydrogen peroxide-water vapor rather than to try to separate the hydrogen peroxide from the water to obtain a water-free hydrogen peroxide vapor). That makes producing a gas-phase mixture having a constant hydrogen peroxide concentration more difficult and also increases the need for analytical methods that can rapidly and accurately indicate the hydrogen peroxide concentration (for monitoring and control). The condensation of hydrogen peroxide is influenced by the presence of water, and condensation of the hydrogen peroxide is something that someone operating a

vapor-phase hydrogen peroxide sterilization process may wish to avoid. That reinforces the need to be able to carefully control sterilization parameters such as temperature and pressure. All of these factors increase the difficulty and complexity of operating hydrogen peroxide vapor-phase sterilization processes and the difficulty and complexity of adequately and properly testing biological and chemical indicators for such processes. (Application, page 2, line 17, to page 3, line 12)

As far as was known to applicants at the time of filing the application, there were no known devices for accurately, reproducibly, and rapidly testing biological and/or chemical indicators for hydrogen peroxide sterilization (and, as far as applicants knew, there were no known standards that anyone contemplating designing such a device could use). (Application, page 8, lines 10-17)

Most advantageously, the present invention provides just such a device. Furthermore, in all cases it can provide an essentially square-wave contact of the sterilization indicators with the antimicrobial gas (i.e., short rise time to reach full concentration of the antimicrobial gas in contact with the sterilization indicators and short fall time to remove all of the antimicrobial gas from contact with the sterilization indicators). The invention can also employ a novel way of generating a substantially constant flow of antimicrobial gas of substantially constant hydrogen peroxide concentration and a novel method to allow calibration of a hydrogen peroxide detection device substantially less expensive than a spectrophotometric device for accurate monitoring of the hydrogen peroxide effluent concentration. In all cases, the invention provides substantially uniform conditions (both spatially and temporally) for the contact

of the antimicrobial gas with the sterilization indicators or other articles. (Application, page 13, lines 15-33)

To achieve the desired square-wave contact, a substantially continuous flow of antimicrobial gas of substantially constant hydrogen peroxide concentration is rapidly or suddenly brought into contact with the materials in question (e.g., biological indicators). That may be accomplished in any feasible manner. For example, the materials to be contacted with the antimicrobial gas may be placed in a chamber and the flow of antimicrobial gas may be rapidly or suddenly diverted into the chamber to commence its contact with the materials. Alternatively, the antimicrobial gas may already be flowing in the chamber and the materials may be rapidly or suddenly moved into the flow of gas in the chamber. Any other suitable scheme may be used. (Application, page 17, lines 4-12)

The invention is believed to provide the first devices that are sufficiently flexible, that are able to rapidly provide uniform conditions, that are precisely controllable, etc. for testing (including conducting research and development activities) for processes and materials (i.e., articles and other materials) in the sterilization field involving hydrogen peroxide. (Application, page 13, line 33, to page 14, line 3)

The Claim Amendments

Claims 1, 15, 16, 23, 29, 30, 32, and 47 have been amended to recite that the concentration of hydrogen peroxide in the antimicrobial gas is "substantially constant as a function of time," the concept of the underlined words already inherently being in the claims by virtue of the definition of "substantially constant" (see application,

e.g., page 19, lines 12-22). Support for these amendments is found in the specification (*id.*) and in original claims 13, 27, and 44. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claim 16 has also been amended to recite "(b) means for suddenly commencing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber and means for continuing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber ...." Support for this amendment is found in original claim 16 and in the specification, e.g., at page 10, lines 9-13.

Claim 29 has also been amended to recite "(b) suddenly commencing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber and continuing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber ...." Support for this amendment is found in original claim 29 and in the specification, e.g., at page 11, lines 6-10.

Finally, applicants have added new method claims 48-50, which depend from method claim 15, new method claims 51-53, which depend from method claim 29, and new method claims 54-56, which depend from method claim 47. These new claims concern the hydrogen peroxide concentration during the time when the antimicrobial gas is contacting the object of interest (e.g., biological indicator) and emphasize the substantially constant level of that concentration, something that is important for accurately, reproducibly, and rapidly testing biological and/or chemical indicators used in hydrogen peroxide sterilization. Support for the new claims is found in the application, e.g., at page 19, starting at line 12:

> With respect to the hydrogen peroxide concentration being substantially constant in the antimicrobial gas in the exposure chamber, "substantially constant" means that over the time period of interest, no concentration within that time period varies from the mean time-averaged hydrogen peroxide concentration over that period by more than plus or minus 15%, desirably by no more than plus or minus 10%, more desirably by no more than plus or minus 8%, most desirably by no more than plus or minus 6%, preferably by no more than plus or minus 4%, more preferably by no more than plus or minus 2%, and most preferably by no more than plus or minus 1%.

It is believed that no impermissible new matter is being introduced by these amendments. Approval and entry of the amendments are respectfully requested.

Objection

Claims 13-14, 27-28, and 44-46 were "objected to as being dependent upon a rejected base claim ..." and were indicated to be allowable if rewritten in independent form etc. (Office Action, ¶ 16 at page 13). In view of the claim amendments and for the reasons discussed herein regarding the patentability of all claims, applicants believe that the objection should be withdrawn.

Rejection Under 35 USC § 112, Second Paragraph

Claims 16 and 29 were rejected under 35 USC § 112, second paragraph. (Office Action, ¶ 2 at page 2), the Examiner saying:

> In claim 16, numbered line 16, applicant recites the phrase "means for suddenly commencing" without specifying what is it that is commencing. Is "commencing" refereeing [sic] to flowing the sterilant? Explanation is needed to understand the meaning of claim 16. The same applies to claim 29. For now, the meaning of "commencing" is to be

interpreted as "commencing the flow of the sterilant gas" in considering claims 16 and 29."

Applicants thought that the language in original claim 16, namely, "means for suddenly commencing and then continuing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber under substantially uniform conditions ...," was clear and would be understood to call for means for doing two things: (1) "suddenly commencing" the contact of the flowing antimicrobial gas etc. and then (2) "continuing" the contact of the flowing antimicrobial gas etc. Applicants also thought the analogous language in claim 29 was clear.

Applicants still believe the language in both original claims is clear but because the Examiner apparently finds it unclear, and to hasten prosecution, "commencing the contact" and "continuing the contact" have been separated and recited in claims 16 and 29 in long form (as opposed to the collapsed form used in the original claims). Thus, apparatus claim 16 now recites "means for suddenly commencing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber and means for continuing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber ...." Method claim 29 has similarly been amended to recite "suddenly commencing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber and continuing the contact of the flowing antimicrobial gas with the one or more sterilization indicators in the chamber ...." Accordingly, it is respectfully submitted that the rejection has been mooted and should be withdrawn.

Rejection Under 35 USC § 102 Of Claims 16, 22, 25-26, 29-31, 33-35, 41-43, And 47

Claims 16, 22, 25-26, 29-31, 33-35, 41-43, and 47 were rejected under 35 USC § 102(b) as allegedly being anticipated by Martens *et al.*, U. S. Patent No. 5,482,684 ("Martens"). (Office Action, ¶ 4 at pages 2-4) For the reasons set forth below, the rejection respectfully is traversed.

The title of Martens is "Vessel Useful For Monitoring Plasma Sterilizing Processes" (emphasis added) and the Abstract of Martens reads as follows (emphasis added):

> A system for testing sterilization processes is provided by a vessel having a chamber, a plasma generator adapted to generate a plasma upstream of the chamber, a monitor associated with the chamber, and a biological or chemical indicator disposable within the chamber. The plasma generator generates upstream plasma that contains a plurality of atomic and/or molecular species, and the monitor is capable of determining a concentration of selected species in the plasma when flowing through the chamber.

In other words, Martens is directed to a plasma sterilizing unit, not a hydrogen peroxide unit. The possible use of hydrogen peroxide as an antimicrobial agent in addition to (not in place of) the plasma is briefly mentioned (column 6, lines 12-16), but as will be discussed below, Martens actually teaches away from the claimed invention.

In making the rejection, the Examiner contended with respect to claims 16 and 30 that:

> the Martens reference discloses an apparatus for testing sterilization processes including the following: a gaseous sterilant includes hydrogen peroxide vapor (col.6, lines 12-13), a chamber (figure 1, 14) with an indicator disposed

> within (abstract, lines 4-5) for contacting with the flowing sterilant (col.7, lines 62-66), means for suddenly commence [sic] flowing the sterilant (col.7, line 12-13 such that suddenly is equivalent to the onset of entry of the sterilant through the inlet 28 into the chamber. Also in col.7, lines 26-35 the Martens reference teaches that sterilization conditions must be established over a very short period of time), continuing the contact with the indicator such that the concentration and the flow of hydrogen peroxide in the sterilant during the contact time is maintained constant (col.7, lines 20-21 and lines 54-58), means for suddenly halting the flow of the gaseous sterilant (suddenly is equivalent to stopping the flow of the sterilant at the end of the cycle, for example, in table I, the indicators were exposed to 2 minutes or 120 seconds) with the indicator after the desired contact time have [sic] passed (Table I, second test is for 2 minutes or 120 seconds), a chamber with articles placed within to be contacted with the flowing sterilant (col.7, lines 62-66), contacting the articles with the gaseous sterilant that includes hydrogen peroxide such that the concentration and the flow of hydrogen peroxide in the sterilant during the contact time is maintained constant (col.7, lines 20-21 and lines 54-58). [Office Action, ¶ 4 at page 3]

The Examiner further contended with respect to claims 22, 25-26, 29, 31, 33-35, 41-43, and 47 that:

> the Martens reference teaches the following: means for monitoring the hydrogen peroxide vapor (figure 1, 26), maintaining [the] indicator or article in a predefined volume in the chamber (gas flowing in chamber 14 in figure 1 is contacting the indicator placed on support 44 such that the indicator is stationed in the imaginary volume), means to flow all of the sterilant gas into the chamber through the predefined volume (the predefined imaginary volume is the volume defined between distributors 34 and 36 in figure 1), a method of testing indicators or sterilization processes by placing the indicator or article in the chamber (col.1, lines 5-8) and suddenly flowing the sterilant (col.7, line 12-13 such that suddenly is equivalent to the onset of entry of the sterilant through the inlet 28 into the chamber. Also in col.7, lines 26-35 the Martens reference teaches that sterilization conditions must be established over a very short period of time) and continuing the contact between the gaseous

> sterilant and the indicator or article under constant concentration and flowing conditions (col.7, lines 20-21 and lines 54-58), suddenly halting the contact between the sterilant and the indicator after the contact time have [sic] elapsed (suddenly is equivalent to stopping the flow of the sterilant at the end of the cycle, for example, in table I, the indicators were exposed to 2 minutes or 120 seconds), means for suddenly commencing (suddenly is equivalent to onset of entry of the sterilant through the inlet 28 into the chamber 14) and then continuing the flow of the sterilant in the chamber (col.7, lines 20-21 and lines 54-58) and means for suddenly halting the flow of the gaseous sterilant includes means for rapidly removing the articles from the chamber (col.8, lines 11-14 such that the door is inherently capable of being rapidly opened and rapidly closed). [Office Action, ¶ 4 at pages 3-4]

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984). Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). "Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990) (emphasis added). The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990) (emphasis added).

As noted above, claim 16 has been amended to expressly recite what was inherently already in the claim, namely, "the concentration of the hydrogen peroxide in the antimicrobial gas during the contact being substantially constant *as a function of time*," and claim 30 has been amended to expressly recite what was inherently already in the claim, namely, "the concentration of the hydrogen peroxide in the antimicrobial gas during the desired time being substantially constant *as a function of time*." (As discussed above, even without the express recital of "as a function of time," that concept was already inherently in each claim because of the definition of "substantially constant": "'substantially constant' means that ***over the time period of interest***, no concentration within that time period varies from the mean time-averaged hydrogen peroxide concentration over that period by more than ..." (application, page 19, starting at line 12; emphasis added).)

Despite that, the rejection fails to identify where in Martens the limitation "substantially constant" (or "substantially constant *as a function of time*") is (or would be) found (there are other differences). Accordingly, the rejection fails to identify where in Martens each and every element of claims 16 and 30 was (and is) shown. The §102(b) rejection (Office Action, ¶ 4 at page 3) contains the bare assertion that "the flow of hydrogen peroxide in the sterilant during the contact time is maintained constant (col.7, lines 20-21 and lines 54-58)." However, the Examiner's asserting that the hydrogen peroxide concentration in Martens is "substantially constant" as defined by applicants doesn't make it so.

The portions of Martens to which the Examiner points to support that assertion mention having uniformity in the sterilization chamber and even reference

"steady state." For example, at column 7, lines 54-58, cited by the Examiner, Martens mentions using a distributor to make the concentration of reactive species "uniform across the sterilization chamber." However, having uniformity "across the chamber" is not the same thing as having uniformity across the chamber from moment to moment. A bare teaching of spatial uniformity is not a teaching of temporal uniformity. Martens in fact recognizes that the sterilizing gas may change as a function of time, which is not consistent with "steady state": "[D]etermining how the intensities of the spectral lines in the plasma change over time gives some indication of how the plasma itself is changing over the same period of time" (Martens, column 9, lines 14-17). As indicated in the claims, applicants need both spatial and temporal uniformity for the contact of the antimicrobial gas with the object being sterilized (e.g., sterilization indicator):

> (c) means for continuing to flow the antimicrobial gas in the chamber to contact the one or more sterilization indicators from substantially the moment they are placed in the chamber, the contact being under substantially uniform conditions for the desired contact time, the flow of the antimicrobial gas during the contact being substantially continuous and the concentration of hydrogen peroxide in the antimicrobial gas during the contact being substantially constant as a function of time ... [Application, claim 1, paragraph (c) (emphasis added)]

Martens states in just a single buried sentence that "the antimicrobial agent may be hydrogen peroxide vapor, such as may be produced *by completely evaporating* 1% to 10% (wt/wt) hydrogen peroxide solution and preferably from 2% to 8% (wt/wt) hydrogen peroxide solution" (column 6, lines 12-16) (emphasis added).[1]

[1] The only "use" in Martens of hydrogen peroxide is in Example 4, which is clearly a *hypothetical* example (emphasis added): "Exposure intervals for exposure to the sterilizing gas will be chosen" (column 13, lines 37-38); "[I]n addition to what is believed to be the primary gaseous oxidizing species of peracetic acid, the *[footnote continued]...*

However, although such evaporation was speculated by Martens to be acceptable for Martens's purposes, such "complete[] evaporat[ion]" will ***not*** result in the "substantially constant" hydrogen peroxide concentration that is *needed* in applicants' invention and is *required* by the claims. As noted in the application (page 2, line 34, to page 3, line 12; emphasis added):

> Hydrogen peroxide has a substantially different vapor pressure curve than water (e.g., its normal boiling point is approximately 151° C as compared to water's normal boiling point of 100° C). Accordingly, differential evaporation (i.e., distillation) may occur when the aqueous solution of hydrogen peroxide is being vaporized. <u>That makes producing a gas-phase mixture having a constant hydrogen peroxide concentration more difficult</u> and it also increases the need for analytical methods that can rapidly and accurately indicate the hydrogen peroxide concentration (for monitoring and control). The condensation of hydrogen peroxide is influenced by the presence of water, and condensation of the hydrogen peroxide is something that someone operating a vapor-phase hydrogen peroxide sterilization process may wish to avoid. This reinforces the need to be able to carefully control sterilization parameters such as temperature and pressure. All of these factors increase the difficulty and complexity of operating hydrogen peroxide vapor-phase sterilization processes and the difficulty and complexity of adequately and properly testing biological and chemical indicators for such processes.

Thus, as will be readily apparent to anyone with even rudimentary knowledge of distillation, the first bit of vapor to be produced (evaporated) from a 1-10% aqueous solution of hydrogen peroxide will be substantially lower in hydrogen peroxide concentration than the last bit of vapor (because of the widely differing volatilities). The

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... [footnote continued]
vapor also <u>may</u> include hydrogen peroxide ..." (column 13, lines 44-46). The words "will be" and "may" are used almost two dozen times in Example 4; there is nothing in Example 4 to indicate that the work
[footnote continued]...

first and last "bits" (portions) of vapor (and many more of the "bits" in between) will differ from the time-averaged hydrogen peroxide concentration by far more than the 15% maximum allowed deviation from the time-averaged hydrogen peroxide concentration. As noted above, applicants' specification teaches at page 19, lines 12-22:

> With respect to the hydrogen peroxide concentration being substantially constant in the antimicrobial gas in the exposure chamber, "substantially constant" means that over the time period of interest, no concentration within that time period varies from the mean time-averaged hydrogen peroxide concentration over that period by more than plus or minus 15%, desirably by no more than plus or minus 10%, more desirably by no more than plus or minus 8%, most desirably by no more than plus or minus 6%, preferably by no more than plus or minus 4%, more preferably by no more than plus or minus 2%, and most preferably by no more than plus or minus 1%. In other words, none of the instantaneously measured concentrations of the hydrogen peroxide deviates from the average by more than plus or minus 15% of the average value, desirably by no more than plus or minus 10% of the average value, more desirably by no more than plus or minus 8%, etc.

It is also important to keep in mind that hydrogen peroxide presents significant additional problems, e.g., it decomposes in the gas phase (see application, page 2, lines 27-34; emphasis added):

> Use of hydrogen peroxide gas-phase sterilizing mixtures presents a number of problems, some of which are unique as compared to the use of older sterilants such as steam and ethylene oxide. For example, hydrogen peroxide immediately starts to decompose as soon as it is vaporized because the stabilizers that help retard or prevent decomposition of the hydrogen peroxide in aqueous solution do not function in the vapor phase (steam and ethylene oxide do not decompose). As a result, hydrogen peroxide

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... *[footnote continued]*
was carried out. The conclusions are inescapable that Martens does not contain any report of the actual use of hydrogen peroxide or of the real world problems its use entails.

> vapor must be generated in "real time" (i.e., as it is needed or on demand), particularly for sterilization processes in which the hydrogen peroxide vapor concentration must be maintained above a predetermined minimum.

One cannot completely evaporate a liquid pool of an aqueous hydrogen peroxide solution of known concentration "x" and expect to have the same concentration "x" of hydrogen peroxide in the vapor phase after the entire pool has been vaporized, because as the hydrogen peroxide evaporates, it starts to decompose.

Martens is completely silent on these problems (e.g., the problem of providing a BIER unit that can adequately and properly test biological and chemical indicators for hydrogen peroxide sterilization processes), neither recognizing those problems nor providing any solution to them, *solutions applicants have found.*

In view of this, it is not surprising that the rejection fails to identify where in Martens each and every element of original claims 16 and 30 is shown (e.g., hydrogen peroxide concentration being "substantially constant" during the contact). Therefore, the rejection is insufficient as a matter of fact and law to support a conclusion of anticipation for claims 16 and 30. The rejection should be withdrawn and should not be repeated for amended claims 16 and 30, which now recite that which was implicit in the original claims (i.e., hydrogen peroxide concentration that is "substantially constant as a function of time").

Furthermore, because the rejection of claims 16 and 30 for alleged anticipation is deficient, the rejection is also deficient as a matter of law with respect to claims 22, 25-26, 29, 31, 33-35, 41-43, and 47, each of which depends directly or indirectly from either claim 16 or claim 30. *See* 35 USC § 112, paragraph four ("[A]

claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."). Therefore, the rejection of dependent claims 22, 25-26, 29, 31, 33-35, 41-43, and 47 should also be withdrawn.

To summarize: the rejection of claims 16, 22, 25-26, 29-31, 33-35, 41-43, and 47 under 35 USC § 102(b) as allegedly being anticipated by Martens is improper and should be withdrawn.

Rejections Under 35 USC § 103

- ***Claims 1, 9-12, 15, 23-24, and 32; Martens in view of Menden***

Claims 1, 9-12, 15, 23-24, and 32 were rejected under 35 USC § 103(a) as being unpatentable over Martens in view of Menden, U. S. Patent No. 6,594,017 ("Menden"). (Office Action, ¶ 8 at page 5)

The rejection respectfully is traversed. At the outset we note that all arguments made in this paper concerning the art, the other rejections, etc. are readopted and reasserted with respect to this rejection as if fully set forth here.

Martens was summarized above.

Menden is entitled "Measuring Sensor Positioning" and the Abstract reads as follows:

> The invention relates to a device and a method for moving a measuring sensor (2) into and out of a pressurized or flow-through conduit (1) or a pressurized or flow-through vessel. The device according to the invention comprises, in this case, a holding element (3) for holding the measuring

> sensor (2), a guiding element (4) for guiding the holding element (3) and a volume element (5). The holding element (3) can be moved in such a way that the measuring sensor (2) held by the holding element comes to rest in a position completely in the volume element (5). In this position, the measuring sensor (2) can be removed from the holding element (3). With the aid of the device according to the invention and the method according to the invention, it is possible, in particular, to measure the cleanliness of a conduit system blown out with a fluid, without the blow-out operation being interrupted.

In making the rejection, the Examiner said that "[t]he teachings of the Martens reference have previously been set forth with regard to claims 16, 22, 25-26, 29-31, 33-35, 41-43 and 47 ..." and then admitted that "with respect to claim 1, the Martens reference fails to teach means for rapidly placing the indicator in the chamber while the flow of the gaseous sterilant is continuous" (Office Action, ¶ 8 at page 6; emphasis added).

The Examiner relied upon Menden to fill the admitted gap, asserting that "[t]he Menden reference, which is in the art of sensing the flow within vessels, teaches moving in and out sensor means while the flow of gas is continuous (col.1, lines 61-67 and figures 1-2, 2)" (*id.*). The Examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor support means of the Martens reference by substituting a measuring sensor that moves in and out of the chamber while the gas flow is continuous for the sensor support means as taught by the Menden so that it is no longer necessary to interrupt the flow of the gas through the vessel (col.2, lines 64-67) to sense the conditions within it." (*Id.*)

The Examiner further stated "[w]ith respect to claims 9-12 and 24, the Martens reference teaches the following: maintaining [the] indicator or article in a predefined volume in the chamber (gas flowing in chamber 14 in figure 1 is contacting the indicator placed on support 44 such that the indicator is stationed in the imaginary volume), means to flow all of the sterilant gas into the chamber through the predefined volume (the predefined imaginary volume is the volume defined between distributors 34 and 36 in figure 1), means for monitoring the concentration of the gaseous sterilant (figure 1, 26), means for maintaining the contact of the gaseous sterilant with the indicator at a desired temperature (col.9, lines 59-60) and means for rapidly removing the indicator or article from the chamber after the desired contact time has elapsed (col.8, lines 11-14 such that the door is intrinsically capable of being rapidly opened resulting in removing the support 44 with the indicator placed on top from the chamber)." (*Id.* at 6-7)

Finally, the Examiner stated that "[w]ith respect to claims 15, 23 and 32, the Martens reference fails to teach placing and removing the indicator or the article while the gas flow is continuous; however, the Menden reference, which is in the art of sensing the flow within vessels, teaches moving in and out sensor means while the flow of gas is continuous (col.1, lines 61-67 and figures 1-2, 2). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor support means of the Martens reference by substituting a measuring sensor that moves in and out of the chamber while the gas flow is continuous for the sensor support means as taught by the Menden reference so that it is no longer

necessary to interrupt the flow of the gas through the vessel (col.2, lines 64-67) to sense the conditions within it." (*Id.* at 7)

The Examiner bears the burden of setting forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). The factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "must be based on objective evidence of record." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002). Furthermore, "[t]o establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03, citing *In re Royka*, 180 USPQ 580 (CCPA 1974).

Here, even if Martens and Menden were properly combinable, which they are not, the proposed combination still would not provide the claimed apparatus. Menden has absolutely nothing to do with sterilization, sterilizing devices, sterilization indicators, or moving anything rapidly into and out of a chamber. In fact, the scheme used by Menden is such that it would hinder rapid in and out movement, which is

required in claim 1 so that square wave contact is achieved (claim 1: "means for rapidly placing the one or more sterilization indicators in the chamber..." and "means for rapidly removing the one or more sterilization indicators from the chamber ..."; also see application, page 13, lines 21-25: "In all cases, the invention can provide an essentially square-wave contact of the sterilization indicators with the antimicrobial gas (i.e., short rise time to reach full concentration of the antimicrobial gas in contact with the sterilization indicators and short fall time to remove all of the antimicrobial gas from contact with the sterilization indicators ...").

Furthermore, as noted above, the original claims required that the concentration of hydrogen peroxide in the antimicrobial gas be substantially constant as a function of time, and the claims that did not already expressly recite "as a function of time" have been amended to expressly recite it. "Substantially constant" with respect to hydrogen peroxide concentration has a specific definition in the application but, as previously explained, Martens does not disclose or suggest the respective claim limitation. Menden certainly does not disclose or suggest it, and the Examiner has not asserted that Menden does. Accordingly, the earlier explanation of why the anticipation rejection fails applies with equal force to this obviousness rejection. There is simply no way any combination of Martens and Menden could render obvious any limitations that neither one discloses or suggests.

This rejection should also be withdrawn (there are other deficiencies in the two documents, but they need not and will not be discussed so as to not overburden the record).

- ***Claim 2; Martens in view of Menden and Richard***

Claim 2 was rejected under 35 USC § 103(a) as being unpatentable over Martens "as applied to claim 1 in view of Menden" and further in view of Richard *et al.*, U. S. Patent No. 6,432,357 ("Richard"). (Office Action, ¶ 9 at page 7)

The rejection respectfully is traversed. At the outset we note that all arguments made in this paper concerning the art, the other rejections, etc. are readopted and reasserted with respect to this rejection as if fully set forth here.

Martens is summarized above.

Menden is summarized above.

The title of Richard is "Sterilizing Gas Compositions Of Ethylene Oxide, Pentafluoroethane And Heptafluoropropane" and its Abstract reads as follows:

> Non-flammable sterilizing gas compositions of ethylene oxide and a flame suppressant comprising pentafluoroethane and heptafluoropropane are useful in the gaseous sterilization of heat and/or moisture sensitive materials. The sterilizing gas compositions are environmentally acceptable and are more efficient and safer to use than conventional sterilant gas mixtures.

In making the rejection, the Examiner acknowledged that "[w]ith respect to claim 2, both the Martens reference and Menden reference ... fail to teach pretreating the indicator before contact with the sterilant gas ..." (Office Action, ¶ 9 at page 7). To try to overcome the admitted deficiency, the Examiner relied upon Richard, asserting that "the Richard reference, which is in the art of vapor sterilization, teaches placing the indicator with the articles in a chamber and then humidifying (pretreating) the articles including the indicator before admitting the sterilant gas (col.5, lines 4-6 and lines 31-44)" (*id.*). The Examiner then concluded that "it would have been obvious to one

having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator pretreatment humidifying step prior to admission of the gaseous sterilant as taught by the Richard reference since such a step is one of the major factors that have to be controlled to have an effective sterilization process (col.5, lines 11-16)" (*id.* at 7-8).

Initially, we note that the rejection fails to identify where in any of the cited documents the limitation in independent claim 1 (from which claim 2 depends) concerning the hydrogen peroxide concentration being substantially constant as a function of time is found. For this reason alone (as explained in detail above), the rejection should be withdrawn, but there are other reasons.

Martens barely mentions the use of hydrogen peroxide and fails to recognize the problems associated with its use or to provide any solution to any of those problems. Menden is totally irrelevant regarding sterilization or BIER units or the problems associated with hydrogen peroxide. Richard is similarly flawed. It deals with a highly specialized sterilization gas composition and has nothing to do with BIER units or hydrogen peroxide or the problems associated with its use.

The Examiner says "it would have been obvious ... to modify the apparatus of the Martens reference by including an indicator pretreatment humidifying step prior to admission of the gaseous sterilant as taught by ... Richard"; however, there is no reason to add a humidifying step to Martens as the Examiner asserts. Certainly the reason the Examiner gives for doing so is inapplicable to Martens. Moreover, while humidification may be needed with the type of sterilant used in Richard (see application, page 5, starting at line 14, regarding ethylene oxide sterilants and the

need for humidification), it is not needed and is actually undesirable in applicants' BIER unit. Thus, the application teaches the following about pre-treatment at page 21, lines 6-12 (emphasis added):

> One desirable pre-treatment may be pre-heating to raise the temperature of the materials above the dew point of the antimicrobial gas prior to their contact with the antimicrobial gas to prevent condensation (e.g., of the hydrogen peroxide). Drying (e.g., by flowing dry gas onto to materials) may be a desirable pre-treatment to reduce the water on and immediately around the materials prior to contact with the antimicrobial gas because the presence of water may cause the hydrogen peroxide to condense out of the gas-phase.

Even if Martens, Menden, and Richard were properly combinable, which is not the case (e.g., there is simply no good reason to combine them), the proposed combination still would not provide the apparatus recited in claim 2, which includes the limitations of claim 1, for the reasons just discussed as well as for the reasons discussed above regarding the requirement that the concentration of hydrogen peroxide be substantially constant as a function of time (e.g., the rejection fails to identify where in Martens, Menden, or Richard that "substantially constant" concentration limitation is found and, therefore, the rejection fails to identify where in Martens, Menden, and Richard each and every element of claim 2 is shown).

As noted above, when patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley*, 60 USPQ2d at 1008. The factual inquiry whether to combine documents

must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433 (emphasis added). The "evidence" pointed to by the Examiner is clearly deficient. "To establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03, citing *In re Royka*, 180 USPQ 580 (CCPA 1974). That is certainly not the case here.

This rejection of claim 2 should be withdrawn.

- ***Claim 3; Martens in view of Menden and Whitbourne***

Claim 3 was rejected under 35 USC § 103(a) as being unpatentable over Martens "as applied to claim 1 in view of Menden" and further in view of Whitbourne *et al.*, U.S. Patent No. 3,992,154 ("Whitbourne"). (Office Action, ¶ 10 at page 8)

The rejection respectfully is traversed. At the outset we note that all arguments made in this paper concerning the art, the other rejections, etc. are readopted and reasserted with respect to this rejection as if fully set forth here.

Martens is summarized above.

Menden is summarized above.

Whitbourne is entitled "Ethylene Oxide Sterilization Indicator" and its Abstract reads as follows:

> A monitoring device for use in ethylene oxide sterilizing systems consists of an envelope containing an indicator coated with a dye, which besides showing a color change on completion of sterilizing cycle also indicates the completion of the subsequent aeration cycle.

In making the rejection, the Examiner admitted that "[w]ith respect to claim 3, both the Martens reference and Menden reference ... fail to teach post-treating the indicator after they have been removed from the chamber." (Office Action, ¶ 10 at page 8) To try to remedy this defect, the Examiner relied upon Whitbourne, saying that "the Whitbourne reference, which is in the art of gaseous sterilization, teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator (post-treating, col.2, lines 61-64)" (*id.*). The Examiner then concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator post treatment aerating step after sterilization as taught by the Whitbourne reference in order to insure that goods are safe to use (col.2, lines 62-64)" (*id.*).

Initially, we note that the rejection fails to identify where in any of the cited documents the limitation concerning substantially constant hydrogen peroxide concentration is found. For this reason alone, this rejection should be withdrawn; however, there are other reasons (e.g., Whitbourne has absolutely nothing to do with hydrogen peroxide or hydrogen peroxide BIER units and teaches nothing about the special problems associated with hydrogen peroxide and its use).

As previously noted, when patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley*, 60 USPQ2d at 1008. The factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the

teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433 (emphasis added). There is no evidence of record to support the proposed combination. Furthermore, "[t]o establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 citing *In re Royka*, 180 USPQ 580 (CCPA 1974). All the limitations of claim 3 are *not* present in the cited art. Even if Martens, Menden, and Whitbourne were properly combinable, which is not the case, the proposed combination would not provide the apparatus of claim 3, which includes the limitations of claim 1. Moreover, the rejection fails to identify where in Martens, Menden, or Whitbourne the "substantially constant" concentration limitation is found. The rejection is insufficient as a matter of law and should be withdrawn.

- ***Claims 4-8; Martens in view of Menden, Richard, and Whitbourne***

Claims 4-8 were rejected under 35 USC § 103(a) as being unpatentable over Martens "as applied to claim 1 in view of Menden" and further in view of Richard and Whitbourne (Office Action, ¶ 11 at page 8).

The rejection respectfully is traversed. At the outset we note that all arguments made in this paper concerning the art, the other rejections, etc. are readopted and reasserted with respect to this rejection as if fully set forth here.

Martens is summarized above.

Menden is summarized above.

Richard is summarized above.

Whitbourne is summarized above.

In making the rejection, the Examiner acknowledged that "[w]ith respect to claims 4-5, both the Martens reference and the Menden reference fail to teach pre-treat [sic] or post-treat [sic] the indicators with the same members." (Office Action, ¶ 11 at page 8). To try to supply the deficiency, the Examiner relied upon Richard, saying that "[t]he Richard reference, which is in the art of vapor sterilization, teaches placing the indicator with the articles in a chamber and then humidifying (pretreating means) the articles including the indicator before admitting the sterilant gas (col.5, lines 4-6 and lines 31-44)" and also asserting that "[t]he humidifying means is part of the chamber sterilization members" (*id.* at pages 8-9). The Examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator pretreatment means prior to admission of the gaseous sterilant as taught by the Richard reference since such a step is one of the major factors that have to be controlled to have an effective sterilization process (col.5, lines 11-16)" (*id.* at page 9).

The Examiner further asserted that "[w]ith respect to claims 4-5, the Richard reference fails to teach post-treating indicators. The Whitbourne reference, which is in the art of gaseous sterilization, teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator (post-treating means, col.2, lines 61-64). The aerating means is part of the chamber sterilization members" (*id.*). The Examiner then concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator post treatment means

after sterilization as taught by the Whitbourne reference in order to insure that goods are safe to use (col.2, lines 62-64)" (*id.*).

The Examiner admitted that "[w]ith respect to claims 6-7, the Martens reference, the Richard reference and the Whitbourne reference all fail to teach the concept of using antechamber that includes pre-treatment and post-treatment by having a movable chamber that moves back and forth between the chamber and the antechamber. The Menden reference discloses antechamber (figure 2, 5) and a movable member (figure 2, 3) and means for moving the movable member (figure 2, 10) back and forth between the chamber and the antechamber (figures 1-2, 5, 1 and 3)." (*Id.* at pages 9-10). The Examiner then concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor support means of the Martens reference by substituting a measuring sensor member that moves back and forth between the chamber and the antechamber for the sensor support means as taught by the Menden reference so that it is no longer necessary to interrupt the flow of the gas through the vessel (col.2, lines 64-67) to sense the conditions within it" (*id.* at page 10).

Finally, as to claim 8, the Examiner asserted that the "Martens reference support means (figure 1, 44) when connected t[o] door (figure 1, 48) as taught in column 8, lines 13-14 is intrinsically capable of rapidly placing and rapidly removing the indicator in the chamber (figure 1, 14)" (*id.*).

As before, the rejection fails to identify where in any of the cited documents the "substantially constant" hydrogen peroxide concentration present in all

of these dependent claims is found. For this reason alone, this rejection should be withdrawn, but there are other reasons.

The Examiner asserts that Richard's humidification pre-treatment occurs in a chamber before admitting the sterilant to that chamber (and, therefore, that the pre-treatment occurs in the sterilization chamber) and asserts that Whitbourne "teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator [for post-treatment]." The Examiner's assertions are inconsistent with the rejection of claim 5, which specifies that "the means for pre-treating and the means for post-treating comprise at least some of the same members."

The Examiner also admits that neither Martens, nor Richard, nor Whitbourne teach using an antechamber but points to volume element 5 of Menden as being applicants' "antechamber," holding element 3 of Menden as being applicants' "movable member," and bar 10 of Menden as being applicants' "means for moving the movable member." In so doing, the Examiner unreasonably tortures the documents and their teachings. Menden has nothing whatsoever to do with sterilization or BIER devices or hydrogen peroxide sterilization, and there is no reason why one skilled in the sterilization art would look to Menden or add an antechamber or movable member to Martens, Richard, or Whitbourne that would be useful as – or be anything like – the claimed antechamber and movable member.

As to claim 8, the Examiner points to Martens, column 8, lines 13-14, and says that reference support means 44 when connected to door 48 is "intrinsically capable of rapidly placing and rapidly removing the indicator in the chamber." In so saying, the Examiner is engaging in pure speculation: there is no teaching in Martens

as to how quickly the door and support means can be moved into or out of the chamber and given that Martens states that the door "is secured in a sealed relationship with the sterilizing chamber" (*id.*), its rapid movement is highly unlikely. Furthermore, the Examiner is forgetting that claim 8 depends from claim 7. There is no way the four documents cited by the Examiner can be mixed together to provide everything called for by claim 8, which incorporates all the limitations of claims 7, 6, 5, 4, and 1. For example, Martens's door and support means are not being moved between a chamber and an antechamber.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley*, 60 USPQ2d at 1008. The factual inquiry whether to combine documents must be thorough and searching. The teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433 (emphasis added). Furthermore, "[t]o establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03, citing *In re Royka*, 180 USPQ 580 (CCPA 1974).

Even if Martens, Menden, Richard, and Whitbourne were properly combinable, which they are not, the proposed combination would not provide the apparatus recited in claims 4-8, which include the limitations of claim 1. Furthermore, the rejection fails to identify where in Martens, Menden, Richard, or Whitbourne the

"substantially constant" concentration limitation is found. The rejection is insufficient as a matter of law and should be withdrawn.

- ***Claims 17 and 36; Martens in view of Richard***

Claims 17 and 36 were rejected under 35 USC § 103(a) as being unpatentable over Martens in view of Richard. (Office Action, ¶ 12 at page 10)

The rejection respectfully is traversed. At the outset we note that all arguments made in this paper concerning the art, the other rejections, etc. are readopted and reasserted with respect to this rejection as if fully set forth here.

Martens is summarized above.

Richard is summarized above.

In making the rejection, the Examiner acknowledged, that "[w]ith respect to claims 17 and 36, the Martens reference fails to teach pretreating the indicator before contact with the sterilant gas" (*id.*). To fill the acknowledged gap, the Examiner relied upon Richard, saying "the Richard reference, which is in the art of vapor sterilization, teaches placing the indicator with the articles in a chamber and then humidifying (pretreating) the articles including the indicator before admitting the sterilant gas (col.5, lines 4-6 and lines 31-44)" (*id.*). The Examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator pretreatment humidifying step prior to admission of the gaseous sterilant as taught by the Richard reference since such a step is one of the major factors that have to be controlled to have an effective sterilization process (col.5, lines 11-16)." (*Id.* at 10-11)

Initially, we note that the rejection fails to identify where in any of the cited documents the limitation in independent claim 16 (from which claim 17 depends) and independent claim 30 (from which claim 36 depends) concerning the hydrogen peroxide concentration being substantially constant as a function of time is found. For this reason alone (as explained in detail above), the rejection should be withdrawn, but there are other reasons.

Martens barely mentions the use of hydrogen peroxide and fails to recognize the problems associated with its use or to provide any solution to any of those problems. Richard is totally irrelevant. It deals with a highly specialized sterilization gas composition and has nothing to do with BIER units or hydrogen peroxide or the problems associated with its use.

The Examiner says "it would have been obvious ... to modify the apparatus of the Martens reference by including an indicator pretreatment humidifying step prior to admission of the gaseous sterilant as taught by ... Richard"; however, there is no reason to add a humidifying step to Martens as the Examiner asserts. Certainly the reason the Examiner gives for doing so is inapplicable to Martens. Moreover, while humidification may be needed with the type of sterilant used in Richard (see application, page 5, starting at line 14, regarding ethylene oxide sterilants and the need for humidification), it is not needed and is actually undesirable in applicants' BIER unit. Thus, the application teaches the following about pre-treatment at page 21, lines 6-12 (emphasis added):

> One desirable pre-treatment may be pre-heating to raise the temperature of the materials above the dew point of the antimicrobial gas prior to their contact with the antimicrobial

> gas to prevent condensation (e.g., of the hydrogen peroxide). Drying (e.g., by flowing dry gas onto to materials) may be a desirable pre-treatment to reduce the water on and immediately around the materials prior to contact with the antimicrobial gas because the presence of water may cause the hydrogen peroxide to condense out of the gas-phase.

Even if Martens and Richard were properly combinable, which is not the case (e.g., there is simply no good reason to combine them), the proposed combination still would not provide the apparatus recited in claims 17 or 36 (which include the limitations of claims 16 and 30, respectively), for the reasons just discussed as well as for the reasons discussed above regarding the requirement that the concentration of hydrogen peroxide be substantially constant as a function of time (e.g., the rejection fails to identify where in Martens or Richard that "substantially constant" concentration limitation is found and, therefore, the rejection fails to identify where in Martens and Richard each and every element of claims 17 and 36 is shown).

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley*, 60 USPQ2d at 1008. The factual inquiry whether to combine documents must be thorough and searching. The teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433 (emphasis added). The "evidence" pointed to by the Examiner is clearly deficient. "To establish *prima facie* obviousness of a claimed invention, all claim limitations must be

taught or suggested by the prior art." MPEP § 2143.03, citing *In re Royka*, 180 USPQ 580 (CCPA 1974). That is certainly not the case here.

This rejection should be withdrawn.

- ***Claims 18 and 37; Martens in view of Whitbourne***

Claims 18 and 37 were rejected under 35 USC § 103(a) as being unpatentable over Martens in view of Whitbourne. (Office Action, ¶ 13 at page 11)

The rejection respectfully is traversed. At the outset we note that all arguments made in this paper concerning the art, the other rejections, etc. are readopted and reasserted with respect to this rejection as if fully set forth here.

Martens is summarized above.

Whitbourne is summarized above.

In making the rejection, the Examiner acknowledged, that "[w]ith respect to claims 18 and 37, the Martens reference fails to teach post-treating the indicator after their [sic] contact with the vaporous sterilant has been halted ..." (*id.*). To try to fill the acknowledged gap, the Examiner relied upon Whitbourne, saying that "the Whitbourne reference, which is in the art of gaseous sterilization, teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator (post-treating, col.2, lines 61-64)" (*id.*). The Examiner then concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator post treatment aerating step after sterilization as taught by the Whitbourne reference in order to insure that goods are safe to use (col.2, lines 62-64)" (*id.*).

Initially, we note that the rejection fails to identify where in any of the cited documents the limitation recited in independent claims 16 and 30 (from which claims 18 and 37 depend, respectively) concerning substantially constant hydrogen peroxide concentration is found. For this reason alone, this rejection should be withdrawn; however, there are other reasons (e.g., Whitbourne has absolutely nothing to do with hydrogen peroxide or hydrogen peroxide BIER units and teaches nothing about the special problems associated with hydrogen peroxide and its use).

As previously noted, when patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley*, 60 USPQ2d at 1008. The factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433 (emphasis added). There is no evidence of record to support the proposed combination. Furthermore, "[t]o establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 citing *In re Royka*, 180 USPQ 580 (CCPA 1974). All the limitations of claims 18 and 37 are *not* present in the cited art. Even if Martens and Whitbourne were properly combinable, which is not the case, the proposed combination would not provide the apparatus of claims 18 or 37. Moreover, the rejection fails to identify where in Martens or Whitbourne the "substantially constant"

concentration limitation is found. The rejection is insufficient as a matter of law and should be withdrawn.

- ***Claims 19-20 and 38-39; Martens in view of Richard and Whitbourne***

Claims 19-20 and 38-39 were rejected under 35 USC § 103(a) as being unpatentable over Martens in view of Richard and Whitbourne. (Office Action, ¶ 14 at page 11)

The rejection respectfully is traversed. At the outset we note that all arguments made in this paper concerning the art, the other rejections, etc. are readopted and reasserted with respect to this rejection as if fully set forth here.

Martens is summarized above.

Richard is summarized above.

Whitbourne is summarized above.

In making the rejection, the Examiner acknowledged, that "[w]ith respect to claims 19-20 and 38-39, both the Martens reference and the Menden reference fail to teach pre-treat [sic] or post-treat [sic] the indicators with same members" (*id.*). To try to overcome this acknowledged deficiency, the Examiner relied upon Richard, saying that "[t]he Richard reference, which is in the art of vapor sterilization, teaches placing the indicator with the articles in a chamber and then humidifying (pretreating means) the articles including the indicator before admitting the sterilant gas (col.5, lines 4-6 and lines 31-44). The humidifying means is part of the chamber sterilization members" (*id.* at pages 11-12). The Examiner then concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

apparatus of the Martens reference by including an indicator pretreatment means prior to admission of the gaseous sterilant as taught by the Richard reference since such a step is one of the major factors that have to be controlled to have an effective sterilization process (col.5, lines 11-16)" (*id.* at page 12).

The Examiner further stated "[w]ith respect to claims 19-20 and 38-39, the Richard reference fails to teach post-treating indicators" (*id.*). To try to fill the admitted gap, the Examiner relied upon Whitbourne, saying that "[t]he Whitbourne reference, which is in the art of gaseous sterilization, teaches removing the articles along with the indicator from the sterilization chamber and placing them in an aerator (post-treating means, col.2, lines 61-64). The aerating means is part of the chamber sterilization members." (*Id.*). The Examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Martens reference by including an indicator post treatment means after sterilization as taught by the Whitbourne reference in order to insure that goods are safe to use (col.2, lines 62-64)." (*Id.* at 12).

As before, the rejection fails to identify where in any of the cited documents the "substantially constant" hydrogen peroxide concentration present in all of these dependent claims is found. For this reason alone, this rejection should be withdrawn, but there are other reasons.

The Examiner asserts that Richard's humidification pre-treatment occurs in a chamber before admitting the sterilant to that chamber (and, therefore, that the pre-treatment occurs in the sterilization chamber) and asserts that Whitbourne "teaches removing the articles along with the indicator from the sterilization chamber and placing

them in an aerator [for post-treatment]." The Examiner's assertions are inconsistent with the rejection of claim 20 and 39, which specify that "the means for pre-treating and the means for post-treating comprise at least some of the same members."

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley*, 60 USPQ2d at 1008. The factual inquiry whether to combine documents must be thorough and searching. The teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433 (emphasis added). Furthermore, "[t]o establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03, citing *In re Royka*, 180 USPQ 580 (CCPA 1974).

Even if Martens, Richard, and Whitbourne were properly combinable, which they are not, the proposed combination would not provide the apparatus recited in claims 19, 20, 38, or 39, which include the limitations of the independent claims from which they depend (i.e., claims 16 and 30). Furthermore, the rejection fails to identify where in Martens, Richard, or Whitbourne the "substantially constant" concentration limitation is found. The rejection is insufficient as a matter of law and should be withdrawn.

- ***Claims 21 and 40; Martens in view of Richard, Whitbourne, and Menden***

Claims 21 and 40 were rejected under 35 USC § 103(a) as being unpatentable over Martens in view of Richard, Whitbourne, and Menden. (Office Action, ¶ 14 at page 12).

The rejection respectfully is traversed. At the outset we note that all arguments made in this paper concerning the art, the other rejections, etc. are readopted and reasserted with respect to this rejection as if fully set forth here.

Martens is summarized above.

Richard is summarized above.

Whitbourne is summarized above.

Menden is summarized above.

In making the rejection, the Examiner admitted that "[w]ith respect to claims 21 and 40, the Martens reference, the Richard reference and the Whitbourne reference all fail to teach the concept of using antechamber that includes pre-treatment and post-treatment means" (*id.* at page 12). To try to remedy the acknowledged defect, the Examiner relied upon Menden, saying that "[t]he Menden reference discloses antechamber (figure 2, 5) and a movable member (figure 2, 3) and means for moving the movable member (figure 2, 10) back and forth between the chamber and the antechamber (figures 1-2, 5, 1 and 3)." (*Id.* at pages 12-13). The Examiner then concluded that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor support means of the Martens reference by substituting a measuring sensor member that moves back and forth between the chamber and the antechamber for the sensor support means as taught by

the Menden reference so that it is no longer necessary to interrupt the flow of the gas through the vessel (col.2, lines 64-67) to sense the conditions within it." (*Id.* at page 13).

As before, the rejection fails to identify where in any of the cited documents the "substantially constant" hydrogen peroxide concentration present in all of these dependent claims is found. For this reason alone, this rejection should be withdrawn, but there are other reasons.

The Examiner admits that neither Martens, nor Richard, nor Whitbourne teach using an antechamber that include pre-treatment and post-treatment means, but points to volume element 5 of Menden as being applicants' "antechamber," holding element 3 of Menden as being applicants' "movable member," and bar 10 of Menden as being applicants' "means for moving the movable member." In so doing, the Examiner unreasonably tortures the documents and their teachings. Menden has nothing whatsoever to do with sterilization or BIER devices or hydrogen peroxide sterilization, and there is no reason why one skilled in the sterilization art would look to Menden or add an antechamber or movable member to Martens, Richard, or Whitbourne that would be useful as – or be anything like – the claimed antechamber and movable member.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO must include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley*, 60 USPQ2d at 1008. The factual inquiry whether to combine documents

must be thorough and searching. The teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433 (emphasis added). Furthermore, "[t]o establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03, citing *In re Royka*, 180 USPQ 580 (CCPA 1974).

Even if Martens, Menden, Richard, and Whitbourne were properly combinable, which they are not, the proposed combination would not provide the apparatus recited in claims 21 or 40, which claims include the limitations of all the claims from which they depend, including independent claims 16 and 30, respectively. Furthermore, the rejection fails to identify where in Martens, Richard, Whitbourne, or Menden the "substantially constant" concentration limitation is found. The rejection is insufficient as a matter of law and should be withdrawn.

CONCLUSION

For the reasons set forth above, entry of the amendments and new claims, withdrawal of the rejections, and allowance of all claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 28, 2005.

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